7/9/01

K003662

Spine Works
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9 April 2001

Food and Drug Administration
Center for Devices and Radiological Health

K003662
Spine Works Collar

Summary Statement

Cervical Orthoses have been used by the spine surgeon for decades to stabilize the cervical spine. Halo-Vest utilize cranial fixation through a circumferential ring (thus, the name, Halo) through which steel or titanium pins are screwed to contact and penetrate the scalp and outer table of the skull at four or more points.

Less cumbersome cervical orthosis include collars which stabilize the spine by encompassing the neck, upper back, sternum and chin. The collars are easy to apply and do not require fixation to the cranium however restrict movement of the mandible and make eating and speaking difficult.

Spine Works has developed an easily applied, low profile, collar type cervical orthosis. Cervical stabilization is obtained by attaching the patients cranium to the posterior of the device with temporary bone screws (316L Stainless Steel). This device allows full movement of the mandible and eliminates the use of compressive pins.

The principal risks of the Halo are the results of the pin fixation. The pins apply compressive forces to the cranium which over time leads to local bone necroses and pin loosening. Further tightening of the fixation pins can cause pin penetration to the dura and even the brain. Pin penetration of the scalp and bone also present a risk of infection.

The Spine Works orthosis uses the upper back, neck and sternum to support a rigid posterior fixation collar extension. Cervical stabilization is obtained by attaching the cranium to the rigid fixation collar. The connection between the cranium and the collar is achieved with bone screws designed with a shoulder/stop to insure against over penetration of the cranium bone. Cranium penetration is avoided by screw length design based on published skull thickness studies, double checked by incremental drilling. Screw fixation to the skull is a standard internal fixation of craniotomy flaps and cranio-cervical internal fixation for certain unstable fractures and arthritis. External fixation of bone is standard practice with such devices as the Agee-WristJack.

The risk of using the Spine Works device is infection at the bone screw locations. The acceptability of this risk is well established by the long experience with halo-vest orthosis. The risks eliminated by this device are inadequate stabilization with present collar devices and fixation pin penetration of the skull with present halo-vest devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL - 9 2001

Mr. Dan Farley
President
Spine Works
10170 E Cherry Bend Road
Traverse City, Missouri 49686

Re: K003662
Trade Name: Spine Works Collar
Regulation Number: 882.5960
Regulatory Class: Class II
Product Code: HAX
Dated: April 9, 2001
Received: April 10, 2001

Dear Mr. Farley:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Celia M. Witten, Ph.D., MD
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Enclosure 1

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510(k) Number (if known): K003662

Device Name: Spine Works Collar

Indications For Use:

Includes stable cervical fractures or dislocations, stable high thoracic fractures or dislocations, cervical sprains or strains, post-operative stabilization of the upper spine, rheumatoid arthristis, and spondylosis or other spine deformities.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative and Neurological Devices

(Optional Format 3-10-98)

510(k) Number K003662